

WHAT IS CLAIMED IS:

1. A process for purifying plasmid DNA from host cell impurities to obtain a DNA product, said process comprising:

- (a) lysing host cells containing the plasmid DNA to obtain a lysate;
- (b) clarifying said lysate to obtain a clarified lysate;
- (c) ultrafiltering said clarified lysate to obtain an ultrafiltered clarified lysate;
- (d) adding a first precipitating agent in sufficient quantity to said ultrafiltered clarified lysate to obtain a precipitate of the plasmid DNA;
- (e) dissolving said precipitate to obtain a first solution;
- (f) adding a second precipitation agent in sufficient quantity to said solution to precipitate the host cell impurities and to obtain a solute containing the plasmid DNA;
- (g) transferring said solute into another buffer to obtain a second solution;
- (h) applying said second solution to an anion exchange chromatography (AEX) material to obtain an eluate containing the plasmid DNA; and
- (i) applying said eluate to a hydrophobic interaction chromatography (HIC) material to obtain the DNA product.

2. The process of claim 1, wherein said AEX material comprises a ceramic matrix.

3. The process of claim 2, wherein an average particle diameter of said ceramic matrix is about 10 μm to about 200 μm .

4. The process of claim 2, wherein an average pore size of said ceramic matrix is about 750 \AA to about 3000 \AA .

5. The process of claim 2, wherein an average pore size of said AEX material is about 10 Å to about 100 Å.

6. The process in claim 1, wherein an average particle diameter of resin for said HIC material is about 50 µm to about 150 µm.

7. The process in claim 1, wherein an average pore size of resin for said HIC material is about 25 nm to about 100 nm.

8. The process claim of 1, wherein said lysing in (a) is by alkaline lysis.

9. The process of claim 1, wherein said clarifying in (b) is by diatomite aided depth filtration.

10. The process of claim 1, wherein said ultrafiltering in (c) is by hollow fiber ultrafiltration.

11. The process of claim 1, wherein said first precipitating agent in (d) is polyethylene glycol (PEG).

12. The process of claim 1, wherein said second precipitating agent in (f) is ammonium acetate.

13. The process of claim 1, wherein said eluate in (h) is adjusted to a concentration of about 1 M to about 2 M ammonium sulfate.

14. The process of claim 1, wherein said HIC material in (i) contains cross-linked agarose resin.

15. The process of claim 1, further comprising concentrating said DNA product in (i) by ultrafiltration.

16. The process of claim 1, further comprising diafiltering said DNA product in (i) to remove ammonium sulfate.

17. The process of claim 1, wherein said DNA product is precipitated with ethanol.

18. The process of claim 1, which is conducted in the absence of any added enzymes, organic extractants, or mutagenic reagents.

19. The process of claim 1, further comprising sterilizing, formulating, and filling in a sterile container said DNA product.

20. The process of claim 1, wherein said host cells are bacteria.

21. A DNA product obtained by the process of claim 1.

22. The DNA product of claim 21, wherein said DNA product contains about 95% or greater by weight of circular plasmid DNA.

23. The DNA product of claim 21, wherein said DNA product contains less than about 5% by weight of RNA.

24. The DNA product of claim 21, wherein said DNA product contains less than about 0.002 μg of host DNA/ μg of DNA product.

25. The DNA product of claim 21, wherein said DNA product contains less than about 0.001 μg of protein/ μg of DNA product.

26. The DNA product of claim 21, wherein said DNA product contains less than about 0.01 EU/ μ g of DNA product.

27. A medicament comprising the DNA product of claim 21.

28. A sterile container containing the DNA product of claim 21.

29. A kit comprising the DNA product of claim 21.

30. A DNA product comprising about 95% or greater by weight of circular plasmid DNA, wherein said DNA product contains less than about 5% by weight of RNA, less than about 0.002 μ g of host DNA/ μ g of DNA product, less than about 0.001 μ g of protein/ μ g of DNA product, and less than about 0.01 EU/ μ g of DNA product.

31. The DNA product of claim 30 for pharmaceutical use.

32. A medicament comprising the DNA product of claim 30.

33. A sterile container containing the DNA product of claim 30.

34. A kit comprising the DNA product of claim 30.